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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/355,664	10/08/1999	MICHAEL SUNDSTROM	10806-96	6767

7590

05/22/2003

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 05/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/355,664

Applicant(s)

SUNDSTROM ET AL.

Examiner

Olga N. Chernyshev

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-10,42 and 43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9 and 10 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-8, 42-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

***Response to Amendment***

1. Claims 1, 2, 5-10 and 42-43 have been amended as requested in the amendment of Paper No. 24, filed on March 17, 2003. Claims 1, 2, 5-10 and 42-43 are pending in the instant application.

Claims 1, 2, 5-10 and 42-43 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on March 17, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

***Claim Rejections - 35 USC § 112***

5. Claims 1, 2, 5-8 and 42-43 stand rejected under 35 U.S.C. 112, first paragraph for reasons of record as applied to claims 1-9 in section 10 of Paper No. 10 and claims 1-2 and 4-9 and 42-43 in section 5 of Papers No. 16 and 22. Briefly, the instant specification, while being enabling for a modified human growth hormone receptor (hGHR) consisting of residues 32-237 or 32-234 or 34-233 of the native hGHR molecule, capable of being crystallized without being complexed to a ligand molecule, does not reasonably provide enablement for a cytokine receptor protein of the Class I Cytokine family modified in the extracellular domain capable of being crystallized without being complexed to a ligand molecule. Please note that a typographical error was made

Art Unit: 1646

in section 5 of Paper No. 16 and claim 5 was excluded from the list of claims rejected under 112, first paragraph. The error was then reiterated in Paper No. 22. However, claim 5 remained rejected for reasons of record as originally articulated in section 10 of Paper No. 10.

Claims 1, 2 and 5-8, as amended are directed to a cytokine receptor protein of Class I Cytokine family, modified in the extracellular domain, wherein at least one terminal segment which contributes to a disordered structure is deleted, such protein being capable of crystallizing without being complexed to a ligand molecule. Applicant submits that "[I]t is well-within the ability of one of ordinary skill in the art to determine which terminal regions of a Class I cytokine receptor contribute to a disordered structure" (last sentence on page 7 of the Response). Applicant further argues that there is a "striking homology of the extra-cellular domain of [Class I Cytokine Family receptor] proteins" (page 8, last paragraph), which would serve as a basis for structural similarity of the claimed modified proteins. These arguments have been fully considered but are not deemed persuasive.

The nature of the invention is the demonstration that modified extracellular domain of hGHR, hGHR<sub>32-237</sub> precisely, can be crystallized without being complexed to a ligand molecule. This finding appears to be novel because it is not recognized in the art that similar modification/truncation of any cytokine receptor protein, including Class I Cytokine family, could enable crystallization in the absence of a ligand. Moreover, it is recognized that the art of crystallization of cytokine receptors is very unpredictable (see, for example, page 2, first paragraph of the instant substitute specification), and that so far all attempts to crystallize a native unliganded molecule of hGHR<sub>1-237</sub> have failed (page 7, third paragraph).

Art Unit: 1646

While the skill level in the art is high, the level of predictability is low. The fact that hGHR has structural homology to various cytokine receptors does not provide a basis for concluding that truncation of an extracellular domain of any cytokine receptor would enable its crystallization without being complexed to a ligand. Furthermore, a skilled practitioner cannot rely upon one working example of successfully crystallized truncated extracellular domain of hGHR and reasonably expect that truncation of a molecular segment of any cytokine receptor protein of Class I Cytokine Family, the segment that needs to be additionally identified, will allow equally successful yield of clear protein crystals.

Applicant's invention is predicated on the finding that modified extracellular domain of hGHR<sub>32-237</sub> precisely can be crystallized without being complexed to a ligand molecule. Applicant further extrapolates this result into a conclusion that deletion of any terminal molecule segment of any cytokine receptor protein of the Class I Cytokine family would lead to a protein that also can be crystallized without being bound to a ligand. Accordingly, it would appear that Applicant provides a single finding (the finding), and then present an invitation to experiment to determine what terminal segments are critical for unliganded crystallization, and, further, if such procedure can be applied to any member of Class I Cytokine family receptor proteins.

A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc. v. Novo Nordisk*, 42 USPQ 2d 100, (CAFC 1997), the court held that:

“[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable” and that “[t]ossing out the mere germ of an idea does not constitute enabling disclosure”. The court further stated that “when

Art Unit: 1646

there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one can not following the guidance presented therein and practice the claimed invention without first making a substantial inventive contribution.

### ***Conclusion***

6. Claims 1, 2, 5-8 and 42-43 are rejected. Claims 9 and 10 are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Application/Control Number: 09/355,664

Page 7

Art Unit: 1646

Olga N. Chernyshev, Ph.D.

May 21, 2003

OC



JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800